Boston Scientific
MICROVASIVE

NOV 1 5 2001

Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508-650-8000
www.bsci.com

SECTION 10
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Contact: Kathleen Morahan
Principal Regulatory Specialist
Date Prepared: August 6,2001

2. Device:

Trade Name: Wallstent RX Biliary Endoprostheses
Common Name: Biliary Stent
Classification Name: Biliary Catheter & Accessories

3. Predicate Device:

BSC Wallstent Biliary Endoprostheses - K000308, K982184, K964119, & K961262

4. Device Description:

The proposed Wallstent RX Biliary Endoprostheses consists of a stent and a delivery catheter. The self-expanding metal stent is delivered endoscopically with the delivery catheter. The stent is a tubular mesh constructed from a biomedical super alloy wire with a tantalum core to allow for visibility under fluoroscopy. The stent is offered bare or covered. The proposed delivery catheter consists of a coaxial tubing assembly that constrains the stent until it is released by retracting the exterior tube assembly. The interior tube of the coaxial system contains a central lumen to accommodate a 0.035" guidewire that exits near the tip of the delivery catheter. Radiopaque markers are located on the interior and exterior tubes to facilitate imaging during stent deployment. The device will be offered in 8mm & 10mm diameters and 40mm, 60mm & 80mm lengths.

5. Intended Use:

The proposed Wallstent RX Biliary Endoprostheses is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

6. Technological Characteristics:

The stent design and materials are identical to the predicate Wallstent Biliary Endoprostheses that is currently marketed by BSC for the same indication. The primary difference between the proposed and predicate devices is in the design of the delivery catheter. In the predicate device the guidewire runs through the entire length of the delivery catheter whereas in the proposed device the guidewire exits through a lumen near the tip of the delivery catheter. This modification allows for a single operator exchange technique.

7. Performance Data:

Bench testing was conducted to aid with the establishment of substantial equivalence of the proposed device to the predicate device.

8. Conclusion:

BSC has demonstrated that the Wallstent™ RX Biliary Endoprostheses is substantially equivalent to BSC's currently marketed Wallstent™ Biliary Endoprostheses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2001

Ms. Kathleen Morahan
Principal Regulatory Specialist
Boston Scientific Corporation
Microvasive Endoscopy
One Boston Scientific Place
NATICK MA 01760-1537

Re: K012752
Trade/Device Name: Wallstent™ RX Biliary Endoprosthesis
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: August 15, 2001
Received: August 16, 2001

Dear Ms. Morahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

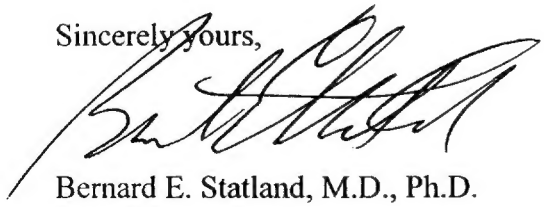
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 1 5 2001

510(k) Number (if known): K012752

Device Name: Wallstent™ RX Biliary Endoprosthesis

FDA's Statement of the Indications For Use for device:

The Wallstent™ RX Biliary Endoprosthesis is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012752